Award Number: W81XWH-09-1-0705

TITLE: "Medical Device Plug-and-Play Interoperability Standards and Technology Leadership"

PRINCIPAL INVESTIGATOR: Julian M. Goldman, MD

CONTRACTING ORGANIZATION: Massachusetts General Hospital
Boston, MA 02114

REPORT DATE: October 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 0704-0188*



| **1. REPORT DATE** *(DD-MM-YYYY)* | **2. REPORT TYPE** | **3. DATES COVERED** *(From - To)* |
|---|---|---|
| October 2017 | Annual | 21 Sept 2016 – 20 Sept 2017 |

**4. TITLE AND SUBTITLE**
"Medical Device Plug-and-Play Interoperability Standards and Technology Leadership"

**5a. CONTRACT NUMBER**

**5b. GRANT NUMBER**
W81XWH-09-1-0705

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**
Julian M. Goldman, MD
Susan Whitehead

Email: jmgoldman@mgh.harvard.edu

**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
Massachusetts General Hospital
Boston, MA 02114-2554

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
U.S. Army Medical Research
and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**
Approved for public release; distribution unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**
This award enabled the MGH Medical Device Plug-and-Play (MD PnP) Interoperability Program to deliver solutions to enable medical device manufacturers, users, and the regulatory community to improve patient safety and healthcare efficiency through interoperable medical technologies. We played a leadership role on interoperability safety standards (AAMI, AAMI/UL Joint Committee 2800), successfully shepherding the ICE standard through its transition from ASTM to AAMI. We obtained further input on the ICE Data Logger ("black box recorder") draft standard and submitted it to AAMI as a New Work Item Proposal, which was accepted. Our research has enabled significant changes to the trajectory of standards and technologies applying interoperability to support patient safety and innovation. Other standards and products are using the ICE standard and will inform future revisions to the ICE and ICE Data Logger standards. We submitted two articles on the relationship between device interoperability and patient safety that were published by the prestigious journal Anesthesia & Analgesia. We expanded exposure of our prototype Clinical Scenario Repository tool and database to clinicians and engineers, showing that the CSR could capture ideas to improve patient safety. These activities leveraged our collaborative work with federal agencies, academia, industry, and standards development organizations.

**15. SUBJECT TERMS**
Medical device, plug-and-play, interoperability, patient safety, device control, health care, standards, regulatory

| **16. SECURITY CLASSIFICATION OF:** | | | **17. LIMITATION OF ABSTRACT** | **18. NUMBER OF PAGES** | **19a. NAME OF RESPONSIBLE PERSON** |
|---|---|---|---|---|---|
| **a. REPORT** | **b. ABSTRACT** | **c. THIS PAGE** | | | USAMRMC |
| U | U | U | UU | 20 | **19b. TELEPHONE NUMBER** *(include area code)* |

## Table of Contents

**Page**

**Annual Report: Medical Device Plug-and-Play Interoperability**
**Standards and Technology Leadership**
**Award Number W81XWH-09-1-0705**
**Principal Investigator: Julian M. Goldman, MD**
**Period of Performance: 21 September 2016 – 20 September 2017**

## Introduction

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device "Plug-and-Play" (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we acknowledged that the need for interoperability encompasses the full continuum of healthcare environments (not limited to the OR), and we developed a strategy to accelerate the development of interoperability technologies, as well as standards. This strategy addressed the need for a "sandbox" laboratory environment to facilitate the testing of devices and technologies with proposed standards; development of a "plug-and-play" system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors' liability and regulatory concerns; and assuring the clinical relevance of all proposed interoperability solutions.

CDMRP support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify, access, and share numerous available resources, and to build collaborations to achieve MD PnP-identified objectives. CDMRP's support has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and NIH. We have created a multi-million-dollar medical device interoperability laboratory in Cambridge, MA as a vendor-neutral, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety, and have exhibited these demonstrations at national meetings and held demonstrations for international audiences in our MD PnP Lab. In 2007, we held our first international conference on "Improving Patient Safety through Medical Device Interoperability and High Confidence Software", jointly sponsored by TATRC and NSF.

Significantly, core program support from CDMRP enabled us to lead the writing of the first medical device integration system safety standard – the Integrated Clinical Environment (ICE) standard, ASTM F2761—Part 1, which includes functional (or logical) architecture and risk mitigation strategies for networked, patient-centric interoperable medical devices. In addition, we led a successful collaborative effort involving four major healthcare delivery organizations to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement of medical device interoperability for improving patient safety by fourteen medical societies (including the American Medical Association). We additionally worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. CDMRP BAA support has been instrumental in providing "program glue" to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

With the FDA and Continua Health Alliance, MD PnP through CIMIT planned and co-sponsored a three-day workshop on Medical Device Interoperability in January 2010. The workshop was attended by over 200 participants from industry, health care, and federal agencies. There has

since been a follow-on working group, which meets regularly under MD PnP leadership, to address safety and regulatory concerns for integrated medical device systems. The FDA organized another meeting on device interoperability with AAMI in 2011, and, in 2012-2013, the FDA initiated a Medical Device Interoperability Coordinating Council to bring together various groups working on different aspects of interoperability. MD PnP played a leadership role in these activities.

## Body of Report

The MD PnP Program has become a recognized leader in demonstrating clinically derived technical solutions for improving patient safety and healthcare efficiency through medical device interoperability. Interoperability will enable the creation of complete electronic health records and will introduce advanced capabilities, such as clinical error resistance, into networked medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support safe interoperability for effective clinical deployment. This requires critical evaluation (or "gap analysis") of potentially suitable candidate standards, as well as the modification of existing standards and the development of new standards for implementation in the MD PnP "standardization framework." By leveraging available standards, we expect to accelerate the MD PnP standards framework development so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the FDA to define interoperability-related hazards and mitigation thereof to help inform regulatory science for networked medical device systems. This has also involved developing the MD PnP Laboratory as a "sandbox" populated with medical devices and test equipment to serve as a vendor-neutral environment to evaluate proposed standards and technologies. Building on our accomplishments to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards Development
- Clinical and Engineering Requirements for Safe Medical Device Interoperability
- Interoperability and Security Requirements for Medical Device Procurement
- Regulatory Science for Safe Medical Device Interoperability
- Management of External Collaborations

Since the program's inception, more than 1000 clinical and engineering experts, as well as representatives of more than 140 industrial and academic institutions, have participated in our plenary workshops / conferences, working group meetings, lab demonstrations, and focus groups to contribute to ongoing program activities that helped shape the common goals.

Option-Year 3 activities under this award have built upon all of our MD PnP program work to date and reflect our vision of progressing medical device interoperability standards, whether specifically ICE-related or more generally applicable, and continuing to develop and make available the clinical requirements for safe medical device interoperability, helping healthcare delivery organizations in general and the DoD in particular with strategies for the procurement of interoperable medical devices, working with the FDA to develop the regulatory science related to integrated medical device systems, and continuing to build the community of interest that will lead to widespread availability and adoption of medical device interoperability for the improvement of patient safety and clinical care. Our work has reached a level of federal interest, national and international recognition, and resource development that underscores our ability to provide strong clinically based leadership in all of these areas.

Aims 2, 5, 7, 8, 10, 11, and 12 were completed for purposes of this award during Option-Year 2.

For Option-Year 3 of this grant, the following set of aims – recast as Tasks – was agreed on with our sponsor as our area of focus:

**Standards Development**

- **Task 1**: Lead transition of ASTM F2761 "ICE" standard to management by a new standards development organization (SDO):

  Participate in 7-12 days of ASTM International and AAMI SDO committee meetings and liaise with senior SDO officers to lead an effective transition of the ICE standards portfolio (ASTM F2761 and future parts) from ASTM to AAMI. Assuring the availability and further development of the ICE standard is important to enable safe standards-based medical device integration for clinical care and equipment management applications of broad importance to the DoD.

  **Deliverable:** Report on the success of the transition

- **Task 2**: Initiate consensus standard for Data Logger (black box recorder) for devices in Integrated Clinical Environments (ICE):

  Develop, draft, submit, and present to a standards development organization a formal "new work item proposal" document to initiate a new consensus standard for medical device data logging in an integrated clinical environment (ICE Data Logger). Base the proposed standard on the analysis of clinical and system requirements and foundational medical device informatics research performed in our MGH / MD PnP Lab in coordination with NIST and the FDA pre-submission initiative. Identify additional engineering requirements via 2-3 meetings and weekly teleconference calls with the AAMI/UL JC2800 standardization committee, and liaison with the AAMI Interoperability Working Group and Medical Device Interoperability Safety Working Group. Data logging is an essential capability to enable continuous quality improvement in integrated clinical environments.

  **Deliverable:** Submission of New Work Item Proposal (NWIP)

**Interoperability and Patient Safety**

- **Task 3**: Submit for peer-reviewed publication an article on the relationship between medical device interoperability and patient safety:

  Include in this paper the potential national impact of reducing preventable medical errors by improving the ability of medical device-health IT systems to reduce preventable adverse events. Analyze published literature, leverage MGH / MD PnP research experience and subject matter experts (SME) community observations as inputs to article.

  **Deliverable:** Submission of article

- **Task 4**: Expanded Release of the Clinical Scenario Repository (CSR):

  The CSR web-based research repository of observations regarding how medical device-HIT integration barriers are impeding the implementation of patient-safety solutions was developed under W81XWH-12-C-0154 and has undergone pilot testing by physician-experts. We will expand the CSR user community to nurse informaticists, clinical

engineers, and DoD clinicians. This will enable further research to refine the research tool's ability to inform opportunities to improve patient safety, and analysis of the effectiveness of the CSR to derive medical device interface and broader device-health IT system requirements. The findings of this research can inform MHS medical equipment procurement guidelines in support of improving healthcare delivery.

**Deliverable:** Enhanced CSR website and report on ability of CSR to generate requirements for improvements to healthcare delivery and medical device procurement

All aims and tasks have been completed for purposes of this grant.

## Research Accomplishments

**Standards Development, Task 1:** Lead transition of ASTM F2761 "ICE" standard to management by a new standards development organization (SDO)

The MD PnP program has continued to play a leadership role in work with various standards development groups, especially the AAMI Interoperability Working Group and the AAMI/UL JC2800 standards for certification of safe medical device interoperability. This Option-Year has enabled significant changes to the trajectory of standards and technologies to leverage interoperability in support of patient safety and innovation, and this input is not limited to the above committees. Several other standards are building on "ICE" (including medical device cybersecurity standards), and will inform changes to future revisions to ICE and the ICE Data Logger standard. (AAMI/UL JC2800 will require data logging based on requirements in the ICE Data Logger standard.)

*Background regarding the need to transition the SDO for the "ICE" standard – ASTM F2761:*
Standard ASTM F2761 describes a logical or functional architecture for platform-based medical device interoperability to enable the use of "apps" and devices to support innovation in clinical care, research, operations, and biomedical device management, and enhance the security of the clinical environment. ASTM F2761 was developed by ASTM Committee F29, based on three years of research performed by the MD PnP program and collaborators, supported by CDMRP. It was the first medical device platform architecture standard and was developed with (FDA) regulatory conformance as a goal. ASTM decided to sunset committee F29, which initiated shepherding the F29 standards portfolio to a new Standards Development Organization (SDO). The F29 portfolio consisted of anesthetic and respiratory equipment (ventilators, anesthesia machines, fluid warmers, etc.) These more traditional device standards in the portfolio were likely to move en masse to a new committee in a new SDO, but ICE required careful consideration of a new "home" to ensure its continued development and effective connection to an emerging portfolio of interdependent standards.

The desired goal of this project was to successfully identify a new standards organization and committee which could adopt and further develop ASTM F2761 "ICE" and any future Parts. Through a series of meetings with the AAMI Senior VP of Standards and the ASTM F29 Executive Committee, we developed a consensus plan. All ASTM F29 standards were transferred to AAMI A/R (Anesthesia and Respiratory equipment), with the exception of the ICE family of standards, which was assigned to the newly formed AAMI Interoperability Working Group (IOWG); both committees are co-chaired by Dr. Goldman. The IOWG offers the benefit of much broader stakeholder participation than the A/R committee, and the placement of ICE there has enabled a number of complimentary standards to be initiated by the experts who constitute the IOWG. As part of the ICE-standards transition plan, Dr. Goldman was appointed to the

AAMI Committee on Standards Strategy (CSS) to provide continued input and direction on the alignment of medical device equipment, interoperability, cybersecurity, and HIT standards.

An IP agreement was reached between ASTM and AAMI to enable future revisions of the ASTM F2761-09(13) ICE standard Part I to be published by AAMI. Future Parts of the ICE standard may be developed within the AAMI Interoperability Working Group (IOWG). The list of proposed parts (subject to change) is currently:

- Part 1: ICE architecture – foundational standard. Published 2009 and 2013, based on research funded by base year of this award
- Part 2: Requirements for network control and equipment interface
- Part 3: Requirements for device models
- Part 4: Requirements for supervision
- Part 5: Requirements for safe and reliable integration
- Part 6: Requirements for Data Logging (initiated under this award – see Task 2 below)

This task is complete.

We have continued to meet with a broad range of experts and stakeholders to share our research learnings and identify content and requirements for standards and technology. In May 2016 we were approached by the VA and asked to participate in the medical device cybersecurity initiative that was formed under a VA-UL CRADA. During this past year, we have been providing the VA CRADA team with subject matter expertise related to medical device interoperability and system safety as they relate to cybersecurity. In April 2017 we hosted an all-day meeting of the VA medical device cybersecurity CRADA team and members of the DoD/VA IPO team in our MD PnP Lab to meet our subject matter experts and see lab demonstrations.

**Standards Development, Task 2:** Initiate consensus standard for Data Logger (black box recorder) for devices in Integrated Clinical Environments (ICE)

*Background on ICE Forensic Data Logging:*
Data Logging of mixed-vendor (heterogeneous) interoperable medical devices – which is medical network "system-level data logging" – is essential to achieve market success by addressing liability concerns and supporting continuous quality improvement of the system of devices. Data logging also drives standardization of interfaces to enable data logger connectivity. One of the key benefits of the ICE standard (F2761) is the provision of a systems architecture to enable complete, time-synchronized data logging. The "ICE Data Logger" is primarily intended for logging to support forensic analysis. F2761 includes an ICE Data Logger in the logical architecture, which served as a placeholder for a future Data Logger standard.

The goal of this task was to work with the AAMI Interoperability Working Group (IOWG) to develop and submit for approval to the AAMI Standards Board, a New Work Item Proposal (NWIP) to initiate a consensus standard for an ICE Forensic Data Logger. AAMI procedure (and good standards-development practice) requires substantial evidence of progress toward a standard prior to submission of the NWIP. We had written a 36-page proposed draft ICE Data Logger standard as part of DoD Award #12277012, and further work on the standard was moved to this award in 2016. With some further work under this award, we had a substantive draft for launching the NWIP submission process.

In a series of AAMI IOWG meetings (chaired by Dr. Goldman), the IOWG refined the ICE Data Logger draft standard to meet committee consensus approval. An ICE Data Logger NWIP was

prepared and submitted to IOWG committee ballot, using the draft data logger standard as foundational supporting content.

Following further document revisions, facilitated by our web-based project site on Basecamp, the IOWG committee unanimously approved the NWIP for submission to the AAMI Standards Board, which meets biannually. Updated NWIP documents were circulated to the Standards Board in October 2016 in preparation for their November 2016 meeting. These updated documents included a strong letter of support from Draeger, and five medical device companies actively participated in this effort.

On initial review, the AAMI Standards Board identified two sections of the draft standard that required modification to meet with their approval. In conference calls with an AAMI standards director, Chair of the AAMI Standards Board, and IOWG subject matter experts, we edited the NWIP, and it was approved in a special meeting of the AAMI Standards Board in November 2016. With the approval of the NWIP, this task is complete.

The technical analysis performed by the IOWG committee is documented in a committee-shared spreadsheet. In addition, two articles were published last year on this work: "Capturing Essential Information to Achieve Safe Interoperability" (Weininger, Jaffe, Rausch, Goldman) in *Anesth Analg* 2016 Jul 6, and "The Importance of State and Context in Safe Interoperable Medical Systems" (Weininger, Jaffe, Robkin, Rausch, Arney, Goldman) in *IEEE Journal of Translational Engineering in Health and Medicine*, 8 July 2016.

Although our deliverable of submission of the NWIP to the AAMI process is complete, we have continued to chair standards meetings and support meeting logistics (e.g. via Basecamp) to mature the ICE Data Logger standard until the end of the period of performance of this award. We will also respond to ICE Data Logger NWIP questions, if posed by the AAMI Standards Board. In June 2017 Dr. Goldman co-chaired a three-day meeting of the IOWG at which substantial progress was made on the ICE Data Logger standard.

**Interoperability and Patient Safety, Task 3:** Submit for peer-reviewed publication an article on the relationship between medical device interoperability and patient safety

Two journal articles were published:

- The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems. Weininger S, Jaffe MB, Goldman JM, *Anesthesia and Analgesia* (published online). DOI: 10.1213/ANE.0000000000001386. Published in *Anesth Analg* 2017 Jan;124(1):127-135

- Capturing Essential Information to Achieve Safe Interoperability. Weininger S, Jaffe MB, Rausch T, Goldman JM, *Anesthesia and Analgesia* (published online.) DOI: 10.1213/ANE.0000000000001351. Published in *Anesth Analg* 2017 Jan;124(1):83-94

By submission of these articles for publication we completed Task 3. We are pleased to report that they were published both online and in print. *Anesthesia & Analgesia* is a prestigious monthly peer-reviewed medical journal established in 1922 and covering anesthesia, pain management, and perioperative medicine. The journal has a 2015 impact factor of 3.827, ranking it fourth out of 31 journals in the category "Anesthesiology."

**Interoperability and Patient Safety, Task 4:** Expand the release of the Clinical Scenario Repository (CSR)

*Background on Clinical Scenario Repository (CSR):*
The CSR is a prototype web-based tool our MD PnP team developed to enable researchers, engineers, clinicians, and patients to describe solutions to healthcare technology gaps that interfere with optimal patient care. The CSR resulted from investigating methods to identify persistent care-delivery gaps that could be addressed through improved interoperability. It became clear to us that the voice of the customer (clinicians, biomedical engineers, patients, and others) could provide detailed information about current or foreseeable problems and also propose solutions if the right tool were available. With DoD funding we developed, and demonstrated an initial web-based prototype; the CSR website and database have been through three iterations based on diverse user feedback and requirements of potential deployment environments. Questions related to management of PHI, governance, stakeholders, and user communities have been investigated. The results have shown that CSR input can spur healthcare improvements by driving the development of new healthcare technologies and refining the implementation of legacy technologies. CSR data can be used to inform compliance/certification criteria for risk-mitigation of specific scenarios, such as persistent hazards or cybersecurity vulnerabilities. The CSR is not intended to replace any mandatory reporting systems.

The goal of Task 4 this past year has been to expand trial usage of our current prototype in order to determine how it might best be further developed. A pilot implementation of the Clinical Scenario Repository (CSR) (aka Good Ideas for Patient Safety) was performed with the physician members of the American Society of Anesthesiologists (ASA) Committee on Patient Safety and Education (CPSE). (The ASA is an educational, research and scientific association of more than 52,000 physicians.) Unique logon credentials were created for the CPSE members, and several web tutorials were held to demonstrate how to use the website. At the annual meeting of the ASA in Chicago in October 2016, the 25 clinical scenarios submitted in the CSR were discussed within the committee, and a plan was formulated to develop a report for ASA leadership. The CPSE reported on the CSR pilot to ASA leadership in a formal committee report.

The ASA CPSE users identified additional usability and data access functions that could be included in a future iteration of the CSR. As the current version of the CSR is still a research build, requirements such as those identified in the ASA pilot will be helpful to develop a more robust version. In addition to the initial intent of using the CSR to identify barriers and opportunities related to device and data integration, we have found that the CSR can be used to capture scenarios related to cybersecurity threats.

In July our MD PnP Interoperability Lab was relocated to an expanded space (3200 sq ft) with greatly expanded networking infrastructure and pre-clinical use case demonstration capabilities, funded by MGH and Partners HealthCare. This enhances the Lab's cybersecurity and interoperability research and operational capabilities, and necessitated moving the servers, including the CSR server.

## Key Research Accomplishments

- **The ICE Standard ASTM F2761-09(13) and its emerging portfolio of related standards have been successfully transferred from ASTM to AAMI.** ASTM, an ANSI-recognized Standards Development Organization (SDO) sunsetted the committee

that developed the ICE standard, requiring a transition to a new SDO. AAMI welcomed the ICE-related standards into the AAMI Interoperability Working Group for standards maintenance and the development of future component parts of the ICE standard portfolio.

- **ICE Data Logger proposed draft standard accepted as New Work Item Proposal by AAMI.** The ICE Data Logger proposed draft standard, which was drafted under Option Year 2, was modified by the Interoperability Working Group and submitted to AAMI to accompany the submission of the ICE Data Logger New Work Item Proposal (NWIP). The NWIP was submitted to the AAMI Standards Board and accepted. As a result of the NWIP, the Interoperability Working Group began formal development of the ICE forensic Data Logger standard.
- **Two peer reviewed papers were published on the relationship between interoperability and patient safety.** These papers detailed the need to understand the system level performance aspects of interoperable systems, the value of basing technical requirements on clinical scenarios, and the importance of using this information to develop safe and usable standards.
- The expanded **Clinical Scenario Repository (CSR)** research pilot demonstrated the value of eliciting clinician user-needs with a self-guiding tool, and using the data as system engineering inputs for interoperable systems.

## Reportable Outcomes

- October–December 2016 – Multiple teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG) to complete the Pre-IDE Supplement submission to FDA
- October–December 2016 – Multiple teleconference calls of the AAMI/UL JC2800 standards committee
- October 13 2016 – DoD/VA Industry Interoperability Roundtable: Interoperability Opportunities
- October 22-24 2016 – American Society of Anesthesiologists Annual Meeting, Chicago, IL. Clinical requirements processes were shared with the ASA Committee on Patient Safety and the Committee on Electronic Media and Information Technology.
- October 26-27 2016 – Wireless Health Conference, held at the NIH (Dr. Goldman is General Co-chair)
- November 10 2016 – IEEE-NIH Special Topics Conference on Healthcare Innovations and Point-of-Care Technologies, Cancun, Mexico
- December 5-9 2016 – Chaired AAMI IOWG and participated in associated committee meetings at AAMI Standards Meeting week, Orlando, FL
- December 2016–March 2017 – Multiple teleconference calls with members of the AAMI/UL JC2800 standards committee
- February 17 2017 – Cyber Wargames, hosted by Smiths Medical
- March 6-10 2017 – Dr. Goldman chaired the IEC/ISO JWG5 Physiologic Closed-Loop Control Systems standard meeting, Arlington, VA. MD PnP research findings on safe interoperability and system integration informed a number of key technical discussions.
- March 7 2017 – Meeting with Dr. Rob Jensen, President of AAMI
- March–June 2017 – Telephone and in-person meetings with AAMI Senior Standards Leadership

- April 7 2017 – DoD/VA Interagency Program Office and members of VA-UL Medical Device Cybersecurity CRADA team participated in all-day meeting with our MD PnP team at our Lab and offices in Cambridge, MA
- May 22-26 2017 – Dr. Goldman chaired the ISO TC 121 international standards meeting for anesthetic and respiratory equipment in Boston. Over 105 delegates from 19 countries participated. Many discussions were held related to medical device interoperability, safety, and security.
- Bi-monthly meetings of the AAMI Interoperability Working Group standard committee

**Presentations on Medical Device Interoperability Topics:**

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

- October 13 2016 – "Safety and Interoperability Innovation," at the DoD/VA Industry Interoperability Roundtable, McLean, VA
- October 25 2016 – Pre-Conference workshop (Co-Chaired with Dr. S. Weininger, FDA) on data trust of medical and health systems, prior to the Wireless Health Conference, held at the NIH
- November 10 2016 – Keynote Speaker, "Interoperability with POC Technologies," IEEE-NIH Special Topics Conference on Healthcare Innovations and Point-of-Care Technologies, Cancun, Mexico
- December 12 2016 – Invited Panelist, "Overcoming Technology Barriers to Precision Medicine," Accelerating Precision Medicine Workshop, Connected Health Conference, Washington, DC
- January 10-14 2017 – Poster presentation on "ICE-based safety interlock to improve the safety of patients undergoing induction of labor," Society of Technology in Anesthesia Annual Meeting, San Diego, CA
- February 19 2017 – Presentation on "MD PnP-led Precision Medicine Initiative Challenge for the Underserved," HIMSS PCHA Conference, Orlando, FL (see PMIChallenge.org)
- January 10-14 2017 – Poster presentation on "ICE-based safety interlock to improve the safety of patients undergoing induction of labor," Society of Technology in Anesthesia Annual Meeting, San Diego, CA
- February 19 2017 – Presentation on "MD PnP-led Precision Medicine Initiative Challenge for the Underserved," HIMSS PCHA Conference, Orlando, FL (see PMIChallenge.org)
- March 2017 – Presentation of ICE standard, CSR and ICE Data Logging research to the biomedical research planning team, Center for Advancement of Science in Space / International Space Station, held at Boston University, Boston, MA
- July 18 2017 – CISA 405(d) Task Group Session (for the Cybersecurity Information Sharing Act of 2015), Washington DC
- July 19 2017 – Panel: Internet of Things in Health and Medicine: Challenges and Opportunities, at IEEE/ACM Conference on Connected Health, Philadelphia, PA
- September 26 2017 – JPC-1 HITI In-Progress Review, Ft Detrick, MD

**Web Site:**

- Our MD PnP web site (currently www.mdpnp.org, new http://mdpnp.mgh.harvard.edu/ in process) is maintained as a major communication vehicle for the program and all major programmatic initiatives, including MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop. The OpenICE project information and downloads of shared documents and code are located at www.openice.info.

**Manuscripts/Publications:**

- The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems. Weininger S, Jaffe MB, Goldman JM, *Anesthesia and Analgesia* (published online). DOI: 10.1213/ANE.0000000000001386. Published in *Anesth Analg* 2017 Jan;124(1):127-135

- Capturing Essential Information to Achieve Safe Interoperability. Weininger S, Jaffe MB, Rausch T, Goldman JM, *Anesthesia and Analgesia* (published online.) DOI: 10.1213/ANE.0000000000001351. Published in *Anesth Analg* 2017 Jan;124(1):83-94

**Conclusions**

Option-Year 3 of this award has enabled significant changes to the trajectory of standards and technologies to leverage interoperability in support of patient safety, cybersecurity, and innovation. Several other standards are building on the ICE standard, and will inform changes to future revisions to ICE and to the ICE Data Logger standard. For example, AAMI/UL JC2800 (for medical device interoperability safety certification) will require data logging based on requirements in the ICE Data Logger standard.

Many companies, researchers, and government representatives have become engaged in this body of work. Several companies are developing ICE-based platforms.

The CSR is a successful proof-of-concept ready for expanded implementation. This progress would have been unlikely without the support of CDMRP.

Despite substantial progress, gaps in standards, technology, and the knowledge-roadmap exist. Research to date has created a solid foundation, but more effort is required to enable industry to effectively engage in such a complex, but much needed, system.

**References**


1. Goldman JM, Jackson JL, Whitehead SF, Rausch TL, Weininger S, “The Medical Device ‘Plug-and-Play’ (MD PnP) Interoperability Program,” part of Schrenker RA, “Software Engineering for Future Healthcare and Clinical Systems,” *IEEE Computer,* April 2006.
2. Goldman JM, “Medical Device Connectivity for Improving Safety and Efficiency,” *American Society of Anesthesiology Newsletter* 70:5, May 2006.
3. Goldman JM, “Patient-Centric Networked Medical Device Interoperability,” part of Dagalakis NG, “Report on the Results of the NIST Medical Devices Metrology and Standards Needs Workshop,” November 2006. http://www.nist.gov/el/isd/upload/USMS_Med_Dev_Needs.pdf
4. Goldman JM, Whitehead S, Weininger S, “Eliciting Clinical Requirements for the Medical Device Plug-and-Play (MD PnP) Interoperability Program,” *Anesthesia & Analgesia* 2006;102:S1-54.

5. Cooney E, “Getting medical devices to talk to each other,” in “White Coat Notes,” *the Boston Globe online*, June 2007. http://www.boston.com/yourlife/health/blog/2007/06/getting_medical_1.html
6. Carr S, “Plug and Play for Patient Safety,” *Patient Safety & Quality Healthcare*, July-Aug 2007. http://www.psqh.com/julaug07/editor.html
7. Lesh K, Weininger S, Goldman JM, Wilson B, Himes G, “Medical Device Interoperability – Assessing the Environment,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, pp. 3-12. IEEE Computer Society Press, 2008.
8. Rausch T, Jackson JL, “Using Clinical Workflows to Improve Medical Device/System Development,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, pp. 133-134. IEEE Computer Society Press, 2008.
9. Schrenker RA, “Ensuring Sufficient Breadth in Use Case Development: How Should Non-Functional Requirements Be Elicited and Represented?” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, pp. 135-136. IEEE Computer Society Press, 2008.
10. Cortés P-A, Krishnan SM, Lee I, Goldman JM, “Improving the Safety of Patient-Controlled Analgesia Infusions with Safety Interlocks,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007)*, *Cambridge, MA, June 25-27, 2007*, pp. 149-150. IEEE Computer Society Press, 2008.
11. Arney D, Goldman JM, Lee I, Llukacej E, Whitehead S, “Use Case Demonstration: X-Ray/Ventilator,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, p. 160. IEEE Computer Society Press, 2008.
12. McBride R, “Doc: Plug-and-play med devices could save lives,” *Mass High Tech* 26:4, p. 7, Jan 18-24, 2008. http://www.bizjournals.com/masshightech/stories/2008/01/21/story11.html?ana
13. Whitehead SF, Goldman JM, “Getting Connected for Patient Safety,” *Patient Safety & Quality Healthcare* 5:1, Jan-Feb 2008.
14. Chiao JC, Goldman JM, Heck DA, Kazanzides P, Peine WJ, Stiehl JB, Yen D, Dagalakis NG, “Metrology and Standards Needs for Some Categories of Medical Devices,” *J. Res. Natl. Inst. Stand. Technol.* 113, 121-129, 2008.
15. Wallroth C, Goldman J, Manigel J, Osborn D, Roellike T, Weininger S, Westenskow D, “Development of a Standard for Physiologic Closed Loop Controllers in Medical Devices,” *Anesth Analg* 106, S-21, 2008.
16. Wallroth C, Goldman J, Manigel J, Osborn D, Weinstein W, Weininger S, Westenskow D, “Development of a Standard for the Interoperability of Medical Devices,” *Anesth Analg* 106, S-23, 2008.
17. Coop CE, Mosher R, Kun L, Geiling J, Grigg E, Long S, Macedonia C, Merrell RC, Satava R, Rosen JM, “Future Delivery of Health Care: Cyber Care,” *IEEE Engineering in Medicine & Biology* 27:6, 29-38, Nov/Dec 2008.
18. Agres T, “Model Contract Gives Momentum to Interoperability Movement,” *Anesthesiology News* 34:12, December 2008.
19. Johnson C, “Medical devices lag in iPod age,” *The Boston Globe*, December 29 2008.

20. Whitehead SF, Goldman JM, “Hospitals Issue Call for Action on Medical Device Interoperability,” *Patient Safety & Quality Healthcare* 6:1, Jan-Feb 2009.
21. Arney D, Goldman JM, Whitehead SF, Lee I, "Synchronizing an X-ray and Anesthesia Machine Ventilator: A Medical Device Interoperability Case Study", *Proceedings of BioDevices 2009*.
22. Anand M, Fischmeister S, Lee I, “Resource Scopes: Toward Language Support for Compositional Determinism,” *Proc. of the 12th IEEE International Symposium on Object/component/service-oriented Real-time Distributed Computing (ISORC)*, Tokyo, Japan, Mar 2009.
23. Fischmeister S, Lam P, “On Time-Aware Instrumentation,” *Proc. of the 15th IEEE Real-Time and Embedded Technology and Applications Symposium (RTAS)*, San Francisco, April 2009.
24. Whitehead SF, Goldman JM, “Connectivity to Improve Patient Safety: Making Medical Device ‘Plug-and-Play’ Interoperability a Reality,” *Patient Safety & Quality Healthcare* 7:1, 26-30, Jan-Feb 2010.
25. Kowalczyk L, “MGH death spurs review of patient monitors,” *The Boston Globe*, February 21 2010.
26. Kowalczyk L, “‘Alarm fatigue’ linked to patient’s death,” *The Boston Globe*, April 3 2010.
27. Arney D, Pajic M, Goldman JM, Lee I, Mangharam R, Sokolsky O, “Toward Patient Safety in Closed-Loop Medical Device Systems,” In: *Proceedings of International Conference on Cyber Physical Systems*, April 2010.
28. Saver C, “Integrating Devices for Patient Safety,” *OR Manager* 26:6, 21-24, June 2010.
29. Fischmeister S, Azim A, “Design Choices for High-Confidence Distributed Real-time Software,” *Proc. of the International Symposium on Leveraging Applications of Formal Methods, Verification and Validation (ISoLA)*, Heraclion, Crete, 2010.
30. Goldman JM, Schrenker R, Melendez L, Hampton R, Driscoll W. Implications of the New FDA Medical Device Data System (MDDS) Regulation for Automated Clinical Documentation. *Proceedings of American Society of Anesthesiologists*: Equipment, Monitoring and Technology. October 2011.
31. Arney D, Goldman JM, Bhargav-Spantzel A, Basu A, Taborn M, Pappas G, Robkin M. Simulation of Medical Device Network Performance and Requirements for an Integrated Clinical Environment. *Biomed Instrum Technol* 2012 Jul-Aug;46(4):308-15. http://mdpnp.org/publications_UN9U.html
32. Arney D, Plourde J, Schrenker R, Mattegunta P, Whitehead SF, Goldman JM. Design Pillars for Medical Cyber-Physical System Middleware. In: Turau V, Kwiatkowska M, Mangharam R, Weyer C, editors. *Proceedings of the 5th Workshop on Medical Cyber-Physical Systems; 2014 April 14; Berlin, Germany*. Dagstuhl: Schloss Dagstuhl; 2014. vol. 36 p. 124-132.
33. Plourde J, Arney D, Goldman JM. OpenICE: An open, interoperable platform for medical cyber-physical systems. In: *Cyber-Physical Systems* (ICCPS); 2014:221.
34. Goldman JM. The Challenge of Acquiring Accurate, Complete, Near-Patient Clinical Data for Data Science Analysis. *NIST Data Science Symposium Proceedings March 4-5 2014, Gaithersburg, MD*; 2014. p. 43-44.
35. Robkin M, Weininger S, Preciado B, Goldman JM. Levels of conceptual interoperability model for healthcare framework for safe medical device interoperability. In: *Product Compliance Engineering* (ISPCE), 2015 IEEE Symposium: 1-8.
36. Weininger S, Jaffe M, Rausch T, Goldman JM. Capturing Essential Information to Achieve Safe Interoperability. *Anesth Analg* Jul 6 2016.
37. Weininger S, Jaffe M, Robkin M, Rausch T, Arney D, Goldman JM. The Importance of State and Context in Safe Interoperable Medical Systems. *IEEE Journal of Translational Engineering in Health and Medicine*, 8 July 2016.

38. Weininger S, Jaffe MB, Goldman JM. The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems. *Anesth Analg* 2017 Jan;124(1):127-135; also published online (DOI: 10.1213/AN E.0000000000001386).
39. Weininger S, Jaffe MB, Rausch T, Goldman JM. Capturing Essential Information to Achieve Safe Interoperability. *Anesth Analg* 2017 Jan;124(1):83-94; also published online (DOI: 10.1213/ANE.0000000000001351).
40. MD PnP web site (currently www.mdpnp.org, new http://mdpnp.mgh.harvard.edu in process)
41. https://www.openice.info/docs/3_apps.html#auto-validate
42. http://mdpnp.org/MD_PnP_Program___MDISWG.html
43. http://mdpnp.org/ebola.htm

**Other relevant documents are linked to from the text of the report.**

**Appendix:** AAMI New Work Item Proposal Form for ICE Data Logger:
*Requirements for the forensic (black box) data logger for an integrated clinical environment (ICE) for Medical devices and medical systems — Basic safety and essential performance of the patient-centric integrated clinical environment (ICE) — Part x: Particular requirements for the forensic (black box) data logger*

# AAMI New Work Item Proposal Form Instructions

Please review existing committee scope and staff responsibilities prior to submitting a New Work Item Proposal: AAMI Technical Committee List

- Where a committee exists, AAMI circulates all New Work Item Proposals to the full committee for review and comment.
- If the proposal does not fall within the scope of an existing committee, AAMI will conduct an additional evaluation to determine if the formation of a new committee, or working group, is necessary.
- If no significant objections are received from committee members regarding the proposal with the work, the NWIP and any supporting documents are sent to the AAMI Standards Board for review and consideration for approval.
- The Standards Board will consider several factors including: whether the work is in AAMI's scope, the need for the new work, the priority of the work for AAMI, the feasibility of completing the work, and whether AAMI has sufficient resources—including stakeholder participation—to undertake the new work.
- If the project is approved, AAMI will notify both the committee, and proposed project leader, as soon as is reasonable and feasible.

## Scope and responsibilities

1. Detailed and accurate Project Title *(but clear and concise)*
2. Please select the type of project being proposed *(insert hyperlink to existing document, use bookmark to ensure link is to a specific section of document referenced)*
3. The scope should define without ambiguity the subject of the document and aspects covered and should be a series of statements of facts. *(Brief summary)* Please recommend proposed project contact.
4. Purpose and Justification

   a. What is the business case for developing this document? (*business*)

   b. What problem, if any, will this standard solve?
5. Relevance to **AAMI's Mission**
6. Documents—n/a
7. What data currently exists or is there a lack of data? *(science)*

   a. List documents
8. List associated documents that should be reviewed/referenced for new work. EG other standards or published papers
9. *(See ANSI Essential Requirements for guidance)* *http://www.ansi.org/essentialrequirements*
10. Go to **Master Committee** List to:

    a. Identify existing committee if applicable

    b. List horizontal committees also interested.

Please submit proposals for new work items, or working groups, to both **standards@aami.org** and the director in charge of the appropriate committee.

**Association for the Advancement of Medical Instrumentation** 4301 N. Fairfax Drive Suite 301 Arlington, VA 22203-1633 **T:** +1-703-525-4890 **F:** +1-703-276-0793 www.aami.org

## SECTION A: Project Information *(Complete all sections to the best of your ability; required for submission.)*

1. Proposed project title: Requirements for the forensic (black box) data logger for an integrated clinical environment (ICE) for Medical devices and medical systems — Basic safety and essential performance of the patient-centric integrated clinical environment (ICE) — Part x: Particular requirements for the forensic (black box) data logger

2. Type of Project (Standard, Technical Information Report, Provisional Standard): Standard

   Other (*please specify*): _____

3. Anticipated use environment (AUE): Not restricted to a particular use environment

   E.g. manufacturing industry use, hospital or healthcare setting, home care setting training material for clinical setting, manual for HTM professionals, reference material in academic environment

   Other (*please specify*):

4. Scope: This standard provides requirements for system data logging capabilities in support of forensic analysis of ICE systems. Data logs, data logging, and data loggers play important roles in the basic safety and essential performance of integrated clinical environments. This standard is intended to provide additional requirements for users and manufacturers of a data logger as described in ASTM F2761-09(2013), subclause 4.2.4, Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model (i.e. ICE standard).
5. This standard specifies general functional and interoperability requirements, a model and a framework for a data logger which is a component in an integrated clinical environment. The standard will identify use cases for the types of data to be collected.
6. NOTE 1 This type of data logger is also referred to as a “black box recorder” in other sectors.
7. NOTE 2 The development activities of this standard are intended to align with related content in ASTM F2761-09(2013) and its successors, be complementary with related AAMI-UL 2800 documents that are under development, and build on several years of research and prototypes that have been funded by US governmental grants in collaboration with NIST.
8. NOTE 3 This standard is intended to be useful for regulatory purposes.

9. Proposed project contact: Michael Jaffe, Cardiorespiratory Consulting, LLC, 410 Mountain Road, Cheshire, CT 06410, Phone: 203-464-3196 (mobile), mjaffe@mdpnp.org, and Julian Goldman, jmgoldman@mgh.harvard.edu 617-395-5692

## SECTION B: Market/Stakeholder Relevance

10. Purpose/justification: Medical devices have had some level of device-level data logging capabilities for decades. The logs may include device performance metrics for technical troubleshooting and maintenance, and clinical data for patient care. The data logs are not standardized as to content or format that makes analysis of the individual logs and the agglomerated logs difficult. These logs are downloaded as needed to perform adverse event analysis, but even if one device log is fairly “complete”, a log of the entire clinical picture including data from all devices in use at that time, is not available. For example, in typical complex clinical environments (e.g. OR, ICU, ED) obtaining time-aligned integration of data streams from multiple devices – each with its own proprietary communication protocols and algorithms, time base, and physical interfaces – offers numerous challenges. An integrated (time coordinated) forensic data logging capability is needed for the entire clinical environment in which the patient is being monitored or is receiving therapy. It should address logging of commands (device button presses and network communication), device connection and disconnection, physiologic and technical alarms, patient physiologic data, and other device status information.
11. The data logging capabilities and characteristics of selected medical devices with varying capabilities – including ambulatory data loggers (e.g. digital Holter recorders), handheld monitors (e.g. combined SpO2 and CO2), laboratory data recorders (e.g. sleep diagnostics systems), multi-parameter respiratory monitors, multi-parameter physiologic monitoring systems, anesthesia workstations, and ventilators – vary significantly with respect to the capabilities, data formats, and bandwidth requirements. Given the wide range and differences in device output data streams and capabilities, the benefits of a standards-driven approach to combine measurements from devices from different manufacturers and sometimes even the same manufacturers should be apparent. This is further complicated by the need for efficient mechanisms for data playback for adverse event/near-miss investigation and reporting. The ability to playback data sets does exist, but is limited in scope. For example, ambulatory ECG recording devices have developed a sophisticated suite of tools for the playback and analysis of ECG data.
12. A data/patient-centric approach as defined in the ICE standard will allow plug-and-play devices using data-centric protocols and an ICE data logger to work seamlessly, in an open, standardized, and time-synchronized manner, as compared to individual device-based approaches. The advantages include more efficient adverse event/near miss analysis, common terminology and time base, and improved security. Such an approach permits new opportunities for improved patient monitoring and safety. This is distinct from the capabilities of the EHR, which uses lower granularity data storage (e.g. one minute) and can fail to capture clinically significant outliers. ICE Data Logging is essential to successful adoption of interoperable medical device systems for at least two reasons: Data must be openly available to be logged, and data logs are important to address manufacturer’s liability concerns by providing information about each device's activity when interoperating in heterogeneous (multi-vendor) systems.
13. With each device uniquely identified electronically (e.g. FDA UDI) and data formatted in a standardized form, new opportunities for improvements in adverse event investigation will be enabled, similar to those enabled by the data recorders used in transportation and flight data recorders. Challenges with current approaches to adverse event analysis, including device location and sequestering, manual data entry, differences in clock timing, and problems with data extraction, are reduced. Debugging logs

including network interactions can facilitate sophisticated debugging of device and operator interactions, which may assist with clinical event analysis. Significant work will be required to develop effective playback tools.*

14. Data recorders have been used for forensic purposes in transportation over the last century and have become required through the development of standards and passage of legislation and/or commonplace in commercial aircraft, automobiles, trains and larger ships. These developments resulted in technical changes, process and cultural changes – as each area works to become a more safety conscious culture with effective safety improvement mechanisms. The most well known and most advanced changes are in commercial aviation with the use of flight data and voice recorders, structured and well-defined and mature methods for accident investigation by an impartial body and a culture willing to work for safety - given so much is at stake for both the passengers and the pilot.
15. *Adapted from Jaffe MB, Arney D, Weininger S, Dain S, Goldman, JM. THE INTEGRATED CLINICAL ENVIRONMENT (ICE) DATA LOGGER – OPPORTUNITIES AND ADVANTAGES RELATIVE TO INDIVIDUAL DEVICE DATA LOGGING. Society for Technology and Anesthesia Annual Meeting, 2014.
16. Existing ICE Data Logging scientific and technical content developed by a group of academic and industry collaborators (several collaborating under an NIH/NIBIB U01 grant to the Massachusetts General Hospital MD PnP program), including prototypes developed by a joint NIST-MGH project will be provided for committee use. See http://mdpnp.org/MD_PnP_Program_DataLogger.html (accessed June 6, 2016) A proposed draft data logging standard document, funded in part by the DOD, will be provided for use by the committee.
17. Draft proposal attached.

18. For relevance to AAMI'S mission: **click here**

19. Select relevant documentation: Proposed Draft
    E.g. Existing Document, Outline, Proposed Draft, None

    Attach documentation to email or provide link to online version in this field: _____

20. Reference/background materials: Purpose/justification adapted from Jaffe MB, Arney D, Weininger S, Dain S, Goldman, JM. THE INTEGRATED CLINICAL ENVIRONMENT (ICE) DATA LOGGER – OPPORTUNITIES AND ADVANTAGES RELATIVE TO INDIVIDUAL DEVICE DATA LOGGING. Society for Technology and Anesthesia Annual Meeting, 2014

21. Known patent issues: _____

22. Intended Audience: [

☒ Industry/Manufacturing ☐ Consumers ☒ Testing/Labs ☒ HDO (Healthcare Delivery Organizations) Clinical Users
☒ Academia ☐ HTM ☒ Outside U.S. ☒ Regulatory
☒ Other *(Please specify):* system integrators

## SECTION C: Consensus Body Considerations

23. Committee considerations:

    ☐ New committee ☒ Existing committee *(If existing committee is selected, check one below):*
    - ☒ Existing work group; existing task group
    - ☐ Existing work group; new task group
    - ☐ New work group

24. For a list of AAMI committee(s)/work group(s), **click here.** Then type your choice(s) here:
    The proposed standard has been identified as a priority by AAMI Interoperability Working Group.The responsibility for the foundational standard for this proposed work, ASTM F2761, has been recently transferred to AAMI and placed in the AAMI SM-WG03 IOWG

25. Additional committee/work group input: This project is proposed to be part of the SM-WG03 Interoperability working group at AAMI. It will be expected that these will be coordination with AAMI/UL 2800, AAMI SM-WG-05 AAMI Device Security WG, AAMI AL and MP, and other groups external to AAMI that are working in the space of Interoperability.

26. Stakeholder outreach: *(Are all stakeholders participating? Do we need input from other associations, clinical user groups, academia etc?)* _____

27. International relevance: (*Does this work relate to, or affect, existing standards or work, e.g. ISO, IEC?)* List appropriate documents.
    We are not aware of any international standards in progress or final with respect to clinical or forensic (black box) data recorders to be used in the clinical environment.
    We do note the work of:
    - AAMI/UL 2800; and
    - Alarm system requirements in the 60601 family (60601-1-8 clause related to alarm system logging) and related 60601 and 80601 series,

    with which we intend to coordinate.

28. Resource Considerations: _____

**SECTION D: For AAMI internal use only**
Proposed development track: _____
Additional resources: _____
Expected publication/release of document: _____
Promotion ideas: _____